

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-588/S-001

21-335/S-003

Chemistry Review(s)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-150 DODP	2. NDA NUMBER 21-335
3. NAME AND ADDRESS OF APPLICANT (City and State) Novartis One Health Plaza East Hanover, NJ 07936-1080 Attention: Robert Miranda Director, Drug Regulatory Affairs Telephone: (973)-781-2282		4. AP NUMBER	
6. NAME OF DRUG Gleevec		7. NONPROPRIETARY NAME imatinib mesylate	5. SUPPLEMENT (S) NUMBER(S) DATES(S) SE8-003 28-Jun-02
8. SUPPLEMENT PROVIDES FOR: a claim of categorical exclusion for an Environmental Assessment to support the use of Gleevec in the treatment of pediatric patients with chronic myeloid leukemia (CML)		9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY antineoplastic	11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>	12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) tablet	14. POTENCY 1 mg	16. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
15. CHEMICAL NAME AND STRUCTURE		17. COMMENTS See page 2 CC: NDA 21-335 HFD-150/Div. File HFD-150/RWood HFD-150/YAHsieh HFD-150/AStaten R/D Init. by:	
18. CONCLUSIONS AND RECOMMENDATIONS It is recommended that the request for a claim of categorical exclusion for an Environmental Assessment should be approved.			
19. REVIEWER			
NAME Yung-Ao Hsieh, Ph.D.		SIGNATURE 	DATE COMPLETED 26-Aug-02
DISTRIBUTION ORIGINAL JACKET <input checked="" type="checkbox"/> DIVISION FILE <input checked="" type="checkbox"/> REVIEWER <input checked="" type="checkbox"/> CSO <input checked="" type="checkbox"/> SUP. CHEMIST <input checked="" type="checkbox"/>			

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/s/

Yung-Ao Hsieh
8/27/02 08:17:20 AM
CHEMIST

Rebecca Wood
8/27/02 09:30:15 AM
CHEMIST